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FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. 05/04/2001 Q64175 6389 09/848,225 Kenichiro Shiroyama **EXAMINER** SUGHRUE, MION, ZINN, CHANNAVAJJALA, LAKSHMI SARADA MACPEAK & SEAS, PLLC. PAPER NUMBER ART UNIT 2100 Pennsylvania Avenue N.W.

1615

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applica	tion No.	Applicant(s)		
			9/848,225 SHIROYAMA ET AL.		AL.	
Office Action Summary		Examin	er	Art Unit		
		Lakshm	i S. Channavajjala	1615		
	AILING DATE of this commun	nication appears on t	he cover sheet with t	he correspondence ad	dress	
Period for Reply					·	
THE MAILING  - Extensions of tir after SIX (6) MO  - If the period for  - If NO period for  - Failure to reply v  Any reply receiv earned patent te	ED STATUTORY PERIOD F G DATE OF THIS COMMUN me may be available under the provisions NTHS from the mailing date of this com- reply specified above is less than thirty (3 reply is specified above, the maximum s within the set or extended period for reply ed by the Office later than three months arm adjustment. See 37 CFR 1.704(b).	ICATION. s of 37 CFR 1.136(a). In no munication. 30) days, a reply within the statutory period will apply and y will, by statute, cause the a	event, however, may a reply to tatutory minimum of thirty (30 will expire SIX (6) MONTHS pplication to become ABAND	pe timely filed ) days will be considered timel from the mailing date of this condition (35 U.S.C. § 133).		
Status					· •	
1)⊠ Respor	nsive to communication(s) file	ed on <u>04 June 2004</u>	•			
2a)⊠ This ac	tion is <b>FINAL</b> .	2b) ☐ This action is	non-final.		٠.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed	in accordance with the pract	ice under <i>Ex part</i> e (	<i>}uayl</i> e, 1935 C.D. 11	, 453 O.G. 213.		
Disposition of C	laims					
4) Claim(s) <u>1-11</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.						
<i>'</i> `	s) is/are allowed.				. •	
	Claim(s) 1-11 is/are rejected.					
•	7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.					
o) Claim(s	s) are subject to restri	cuon and/or election	requirement.			
Application Pap	ers				•	
9)∐ The spe	ecification is objected to by th	e Examiner.			•	
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicar	nt may not request that any obje	ection to the drawing(s	) be held in abeyance.	See 37 CFR 1.85(a).		
<u> </u>	ment drawing sheet(s) including	•	-, ,	•		
11)⊡ The oat	h or declaration is objected t	o by the Examiner. I	Note the attached Of	fice Action or form P1	Г <b>О-152</b> .	
Priority under 3	5 U.S.C. § 119				:	
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
· _	Certified copies of the priority	documents have be	en received.			
2.□ 0	Certified copies of the priority	documents have be	en received in Appli	cation No		
	Copies of the certified copies application from the Internation			eived in this National	Stage	
* See the a	attached detailed Office action	on for a list of the ce	rtified copies not rec	eived.		
Attachment(s)			».	(272 / 423)		
	ences Cited (PTO-892) sperson's Patent Drawing Review (I	PTO-948)	4) Interview Sumn Paper No(s)/Ma	nary (PTO-413) ail Date		
	closure Statement(s) (PTO-1449 or			nal Patent Application (PTC	<b>)-152)</b>	

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### **DETAILED ACTION**

Receipt of amendment and remarks dated 6-4-04 is acknowledged.

Claims 1-11 are pending.

The following rejection of record has been maintained:

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al (US 5294444) in view of Kaneko et al (WO 98/27958).

A complete rejection can be found in the previous action.

### Response to Arguments

Applicant's arguments filed 6-4-04 have been fully considered but they are not persuasive.

Applicants traverse the instant rejection stating that one of an ordinary skill in the art would not be led to the present invention because Nakamura requires a combination of amphipathic lipid (which may be a ceramides), a non-ionic surfactant, an ionic surfactant and an aqueous medium, the latter substantially including polyhydric alcohols and alcohols. In contrast, applicants argue that instant invention requires a combination of a specific ceramide, a long-chain fatty acid, a nonionic surfactant and water, but not any other component along with water to obtain a clear, transparent state. It is argued that Nakamura essentially requires polyhydric alcohols and ionic surfactants, whereas in the instant invention, while the former is not essential, the latter may result in skin irritation.

Applicants' arguments are not persuasive because it is only speculative that ionic surfactants may cause irritation but not definitely shown. Applicants have not

cited prior art of record.

established the adverse effects of the composition due to the presence of either the ionic surfactants or of polyhydric alcohols of the prior art. Further, the argued superiority of the present invention in load and costs on the environment are not claimed in the instant claims. Applicants argue that the examples of Nakamura result in a semi-transparent or transparent compositions, whereas all of the instant compositions, except the 3% ceramides (almost transparent), result in clear transparent composition.

Applicants' conclusion that the a semitransparent product but not a transparent composition is achieved by Nakamura is not persuasive because applicants themselves state that Nakamura discloses a transparent or semitransparent composition and further

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# Claim Rejections - 35 USC § 112

applicants have not provided any experimental or comparative evidence to show that

the composition of the prior art can only be semitransparent and not transparent as

claimed. Therefore, it is examiner's position that instant claims are obvious over the

Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants' argument regarding the phrase "consisting essentially of" has been considered. While, the transition phrase allows for the presence of other ingredients, the claim is still deemed to be indefinite because the component D is repeated twice in the claim. It is unclear if the composition of claim 5 contains a compound selected from

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sterol or a polyhydric alcohol as different entities and if so, it is unclear how. A clarification and appropriate correction is requested.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lakshmi S Channavajjala

Examiner Art Unit 1615

February 22, 2005

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Gollamudi S. Kishore, PhD Primary Examiner Group 1500

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